

**Remarks**

Claims 1-4, 7-11, 30, 31, 34-36, 42, 43, 49, 55, 59, and 64 are pending in the application. The Office Action has maintained a prior 35 USC §103 rejection made over Aebi et.al., (hereinafter, Aebi) that was originally withdrawn by a prior examiner, and included new grounds for §112 rejections. In response to the Office Action, Applicant has amended claims Claims 1-4, 7-11, 30, 31, 34-36, 42, 43, 49, 55, and 59. Reconsideration of the captioned application in light of the foregoing amendments and following remarks is courteously requested.

**35 USC §103**

The Office Action has rejected claim 1, in view of Aebi, when R<sup>1a</sup> of the present invention is an ethyl moiety. Applicant respectfully reminds Examiner of *Takeda et.al.*, that the CAFC, in view of *KSR et.al.*, recently held that closely related compounds are not prima facie obvious, and that it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound. *Takeda Chemical vs. Alphapharm* (Fed Cir., No. 06-1329, 2007). Although Applicant stands by their original argument presented in the earlier response, in a good faith effort to expedite the application to allowance, Applicant has amended claims 1, 7, 8, 30, 34, and 35 by deleting moieties when R<sup>1a</sup> is hydrogen or (C<sub>1</sub>-C<sub>8</sub>)alkyl and when R<sup>1</sup> is optionally substituted by (C<sub>1</sub>-C<sub>4</sub>)alkyl.

**35 USC §112**

The Office Action rejected claim 42 as being indefinite under §112 ¶12<sup>nd</sup>. Applicant amended the claim to correct the substituent listing to delete the R<sup>1a</sup> typographical error and replaced it with R<sup>1c</sup>. Applicant has included the definition of R<sup>1c</sup> in the claim, as fully supported by the specification, page 5, lines 1-2, therefore making the rejection moot.

Further, the Office Action rejected claims 1-4, 7-11, 30, 31, 34-36, 42, 43, 49, 55, 59, and 64 as being non-enabled under 35 USC §112 ¶1, for making solvates and hydrates of the claimed compounds. Applicant argues that the solvates and hydrates of said claimed compounds are inherent, are within the scope of the claimed subject matter, and are therefore enabled. However, to expedite examination and allowance of the application, Applicant has amended the claims, making the rejection moot.

Applicant appreciates Examiner's acknowledgement that the specification enables compounds wherein R<sup>1</sup> and R<sup>9</sup> are aryl (phenyl) with halogen or methoxy substituents, or R<sup>4</sup> to be

an alkyl, halogen substituted alkyl or a cycloalkyl. However, the Office Action alleges that claims 1-4, 7-11, 30, 31, 34-36, 42, 43, 49, 55, 59, and 64 are not enabled under 35 USC §112 ¶1 for R<sup>1</sup>, R<sup>0</sup>, or R<sup>4</sup> to be a heteroaryl or other substituent or chemical moiety selected from alkyl, C<sub>3</sub>-C<sub>8</sub> carbocyclic ring, C<sub>3</sub>-C<sub>8</sub> heterocycle, aryl, or heteroaryl that may be optionally substituted. Applicant does not acquiesce to the propriety of the rejection and therefore Applicant respectfully traverses this rejection because there is no evidence of record suggesting that those skilled in the art would not be able to practice the claimed invention. Applicant submits that the analogous compounds with other alkyl, C<sub>3</sub>-C<sub>8</sub> carbocyclic ring, C<sub>3</sub>-C<sub>8</sub> heterocycle, or heteroaryl with optional substitutions can be prepared using the same methods that are amenable to the construction of aryl substituted compounds as described by Schemes I-VII (pages 18-28). Moreover, methods for synthesis of compounds with these substitutions were well known to those of skill in the art as of the effective filing date of the present application. For example, the compounds methyl-, ethyl-, cyclobutyl-, cyclopentyl-, cyclohexyl-, cycloheptyl-, and cyclooctyl-hydrazine, and piperidine-4-hydrazine are all commercially available reagents that enable R<sup>0</sup>. Further, the specification (Scheme 6, page 27, lines 10-21) recite a method for preparing compounds wherein R<sup>4</sup> are optionally substituted piperidinyl or pyrrolidinyl moieties. Therefore, Applicants urge that the specification provides suitable guidance for the skilled artisan to make and use the compounds of the invention e.g., by using the methods of synthesis and assays disclosed in the specification. The specification also provides numerous working examples, demonstrating that any experimentation required to prepare other compounds is not undue, but merely routine. Moreover, even complex experimentation is not necessarily undue if those skilled in the art typically engage in such experimentation. *In re Certain-Limited Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174. Applicant respectfully submits that numerous other embodiments, e.g., R<sup>1</sup> and R<sup>4</sup> substituents can be obtained using the same methods of preparation. The Examiner is respectfully reminded that the number and variety of examples is irrelevant if the disclosure is "enabling" and sets forth the "best mode contemplated" See *In re Borkowski et al.* 442 F2d. 904, 164 USPQ 642 (CCPA 1970). Accordingly, Applicants urge that sufficient disclosure has been provided to fully enable a skilled artisan to practice the claimed invention.

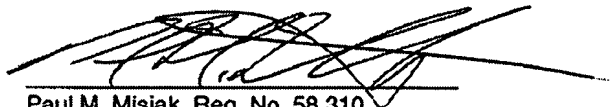
As the specification provides description, examples and synthetic schemes sufficient to teach one of skill in the art how to prepare the compounds, evaluate the compounds, and use the compounds, nothing more is required. *In re Wands*, 8 USPQ2d 1400 (Fed Cir. 1988). Therefore, Applicants submit all bases for rejections under 35 USC §112 have been overcome by claim amendments and aforementioned arguments, and that such rejections should be withdrawn.

Serial No. 10/823,152  
Attorney Docket No. PC25808A

For the foregoing reasons, Applicant submits that the claims are in condition for allowance and respectfully requests the same. The Examiner is invited to contact the Applicants' attorney at the telephone number provided below to discuss any questions or aspects of the present case.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Paul M. Misiak', is written over a horizontal line.

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